

REMARKS

Reconsideration is requested.

Claims 22-41 are pending. Claims 23-26, 28, 34 and 35 are indicated as having been withdrawn from consideration. While claims 34 and 35 are indicated above as having been withdrawn, clarification is requested with regard to the withdrawal of claims 34 and 35 from consideration. Claims 34 and 35 were indicated in the previous Office Action dated October 28, 2009 as reading on the elected species. See page 2 of the Office Action dated October 28, 2009. Neither claims 34 nor 35 were amended in the Amendment of January 28, 2010 or the Supplemental Amendment of February 1, 2010 - which were filed in response to the Office Action of October 28, 2009 - such that the Examiner's withdrawal of the claims from consideration, for the first time in the final Office Action of May 7, 2010, is not appropriate or justified. A Rule 144 Petition for review and consideration of the Examiner's action in this regard is filed concurrently herewith. The Examiner comments on page 2 of the Office Action dated May 7, 2010, that

"claims 23-26, 28, and 34-35 are withdrawn from consideration pursuant to Markush practice as not being anticipated by the art below."

Clarification as to the cause or purpose in withdrawing admitted novel claims from consideration is requested.

Moreover, as claims 36-41 and new claim 42 depend from claim 34, the status of these dependent claims is uncertain in view of the Examiner's withdrawal of claim 34 from consideration.

An early and favorable consideration of the concurrently-filed Rule 144 Petition are requested.

Claims 22-33 have been canceled, without prejudice, above. Claims 36-38 have been amended, without prejudice, and claim 42 has been added, based on the unamended claim 37. No new matter has been added. Claims 34-42 will be pending upon entry of the present Amendment. Entry of the present Amendment is requested.

The Section 112, first paragraph "enablement", rejection of claims 37-41 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following comments.

The Examiner asserts, as a basis of the rejection, that the claims

"claim the use of millions of compounds disclosed in the genus of formula I as HDAC inhibitors". See page 2 of the Office Action dated May 7, 2010.

In fact, the unamended and rejected claims 37-41 refer to the specifically enumerated compounds of claim 34. Moreover, among the eleven (11) specifically defined compounds of claim 34, the HDAC activity of four (4) is assessed in Example 12 and the remaining seven (7) compounds are structurally related such that one of ordinary skill in the art would reasonably expect similar biological activity. The Examiner has not provided any technical or scientific basis for a contrary belief.

As for the Examiner's assertion of an alleged lack of data, the applicants note that biological results provided in the application are IC₅₀ values towards HDAC activity of the claimed compounds. The compounds are compared to reference compounds as IC₅₀ values of 1.4± 0.5nM and 20 nM are measured respectively for trichostatin A and

SAHA. One of ordinary skill will appreciate that these results are sufficient to assess the HDAC inhibitor character of the claimed compounds. See for example, page 64 of the specification.

As for the assertion of the Examiner that HDAC profiles against a reference compound would be necessary to prove the effect, the applicants submit that processing HDAC profiles was not routine practice at the time of the present invention. The 2 classes and 11 sub-types of HDAC were not necessarily all known at the time. The HDAC activity was classically evaluated using assay kits such as are described in the present application (HDAC fluorescence activity assay/Drug Discovery Kit developed by Biomol), and compared to one of SAHA and/or trichostatin A. Publications disclosing HDAC activity of compounds did not mention at the time any profiling, but relied on evaluation of the global HDAC activity. Further, the technical specification of the kit used in the application (copy attached) specifies that

"the assay has been used successfully with preparations of all the known class I HDACs - HDAC 1, HDAC 2, HDAC 3 and HDAC 8 [...] with class II HDACs 4-7, 9 and 10 and with the human Sir2 homolog SIRT 1".

Consequently, whatever the isoform of HDAC on which they have activity, screened compounds will be identified as HDAC inhibitors by this assay. Assaying the claimed compounds with such an assay kit and comparing results to those obtained for reference compounds is therefore sufficient to demonstrate their function as HDAC inhibitors.

The claims are supported by an enabling disclosure. One of ordinary skill in the art will be able to make and use the claimed invention without requiring undue

experimentation. Entry of the present Amendment and withdrawal of the Section 112, first paragraph, rejection are requested.

To the extent not obviated or made moot by the above amendments, the Section 102 rejection of claims 22, 27, 29-33 and 36-41 over U.S. Patent No. 4,829,080, is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following comments.

Entry of the present Amendment will make the Section 102 rejection moot with regard to claims 22, 27 and 29-33. The Examiner has admitted, as noted above, that the compounds of claims 34 and 35 are novel over the cited art. Claims 36-41 require the novel compounds of claim 34, which are not found in the cited art. The cited art therefore fails to teach each and every aspect of the claimed invention. Withdrawal of the Section 102 rejection is requested.

Entry of the present Amendment and allowance of claims 34-42 are requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required.

Respectfully submitted,

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